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PATENT
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: SORENSEN, Marinus B.

Appl. No.: 09/419,927

Examiner: Hamud, F.

Filed : October 18, 1999

Art Unit: 1647

For : PROTEIN EXTENSIN AND METHOD FOR CYTOTOXIC
ENHANCEMENT OF LYMPHOCYTES

Attorney Docket No.: MCG046US

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AUG 08 2002

APPELLANT'S BRIEF

TECH CENTER 1600/2900

Commissioner for Patents
Washington, D.C. 20231

Sir:

The applicant/appellant appeals to the Board of Patent Appeals and Interferences from the "final" decision of January 4, 2002, from the Examiner for the above-identified application.

The Notice of Appeal with the official fee was filed on April 4, 2002. An extension of time for two months with the official fee of \$200 accompanies this brief.

The official fee of \$160 for this brief is also enclosed. If the amounts of the accompanying checks are incorrect, please charge or credit Deposit Account Number 12-1210.

1. Real Party In Interest

The real party in interest for this application is New Nordic Danmark APS, a corporation of Denmark, which has a place of business at Ny Ostergade 11, 4, DK-4000 Roskilde, Denmark. The assignment for the invention and application is

Recorded in the Patent and Trademark Office.

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2. Related Appeals And Interferences

There are no other related appeals or interferences known to the appellant, the appellant's legal representative, or assignee.

3. Status Of Claims

Claims 4 through 9 as presented by the appellant in the response of November 14, 2001, are pending and are the subject of this appeal. The prosecution history behind this status of the claims is as follows.

The application was filed on October 18, 1999, with claims 1 through 3.

An Office Action of May 7, 2001, applied a restriction requirement, which separated each of the three claims into a separate one of three groups. The appellant elected with traverse, in a response of June 7, 2001, to prosecute claim 1, which formed group I of the restriction requirement.

The Examiner made the restriction requirement "final" in an Office Action of August 14, 2001, and withdrew claims 2 and 3 from consideration.

The appellant cancelled claims 1 through 3 in a response of November 14, 2001, and presented claims 4 through 9. These claims are the subject of this appeal.

The Examiner presented a "final" rejection of claims 4 through 9 in an Office Action of January 4, 2002. This

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The appellant presented a proposed amendment to claim 4 in a response of April 4, 2002. The Examiner's Advisory Action of May 6, 2002, refused to enter this amendment.

4. Status Of Amendments

The appellant presented a proposed amendment to claim 4 in a response of April 4, 2002, that was subsequent to the Office Action of final rejection of January 4, 2002. The Examiner's Advisory Action of May 6, 2002, refused to enter this amendment.

5. Summary Of Invention

The invention is a composition for enhancing the immune system. (See the application on page 4 at lines 23 through 26.) The composition is extensin or a combination of (a) pectin or polysaccharides found in the pectic molecule and (b) extensin. The appellant's claimed extensin lacks a tetra-hydroxyproline block. (See the application on page 8 at lines 17 through 21 as amended by the response of November 14, 2001.) The composition induces the development and maturation of extrathymic lymphocytes as explained below.

The appellant performed in vitro experiments to establish the synergistic effects of pectic molecules and extensin. The appellant's experiments identified that a combination of pectic molecules with the protein extensin containing valine, tyrosine, histidine, threonine, and lysine can activate

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lines 21 through 28 as amended by the response of November 14, 2001.) The invention demonstrates that a combination of pectin with extensin "in a ratio higher than seen in natural plant cells" can be used as a therapeutic method to modulate immune responses in the treatment of a broad variety of disorders including infections and cancers. (See the application from page 10 at line 28 through page 11 at line 3 as amended by the response of November 14, 2001; on page 13 at lines 13 and 14; and on page 14 at lines 20 and 21.)

6. Issues

**A. Claim Rejection Under 35 U.S.C. § 112,
Second Paragraph**

The Examiner rejects claims 4 through 9 under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner requests clarification in claim 4 of the terms "being absent a tetra-hydroxyproline block" and "in a pharmaceutically active concentration." The applicant maintains that the language of claim 4 is understood within the art. The amendment proposed by the applicant to overcome this rejection was not entered.

B. Claim Rejection Under 35 U.S.C. § 102(b)

The Examiner rejects claims 4 through 9 under 35 U.S.C. § 102(b) as being anticipated by an article from Plant Physiology by Li et al. The appellant maintains that the

sufficient for cytotoxic enhancement of lymphocytes. The

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article does not disclose the claimed therapeutic activity for the composition. The article to Li et al., therefore, does not anticipate the all the elements of the appellant's claimed extensin.

The appellant did not amend claims 4 through 9 in response to the rejection based upon anticipation and a citation of art. No rejection under obviousness was presented or argued.

C. Technical Bases For Appeal

The appellant also appeals the Examiner's decision for three technical errors of the Examiner. It is maintained that the Board should return the application to the Examiner for further prosecution, before the Board considers this appeal, because of these three technical errors.

The appellant twice requested an interview with the Examiner. No interview was granted.

The appellant's amendment to claim 4 in the response of April 4, 2002, only presented amendments to overcome the Examiner's rejection under 35 U.S.C. § 112, second paragraph. The Examiner then refused entry stating that a "new search" would be required. However, the Examiner presented a new citation of art apparently from a new search.

The appellant also objects to the facts that the Examiner substituted a new citation of art and made the rejections of

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7. Grouping Of Claims

Each of the Examiner's two rejections of the claims rejects claims 4 through 9. The claims of the group do not stand or fall together and are separately patentable as explained more fully below. In particular, the Examiner's rejection under 35 U.S.C. § 112, second paragraph, is largely and independently mooted by claim 6. Claims 5 and 7 through 9 independently overcome the Examiner's rejection under 35 U.S.C. § 102(b) for anticipation by introducing additional claimed elements not found in the Examiner's citation.

8. Argument

A. Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejects claim 1 under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner requests clarification of the terms "being absent a tetra-hydroxyproline block" and "in a pharmaceutically active concentration."

The applicant maintains that the Examiner's rejection is in error because the language of claim 4 is understood within the art. The best evidence in the record that these terms are understood in the art is the Examiner's first citation, which is an article from Plant Physiology by Qi et al., and the Examiner's second citation, which is an article from Plant Physiology by Li et al.

extensin, to which this article is directed, as including

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"blocks of peptide sequences" having four or more hydroxproline peptides. These extensin sequences are "(a) serine-Hyp-Hyp-Hyp-Hyp-Hyp-Hyp-serine-Hyp-Hyp-lysine, (b) serine-Hyp-Hyp-Hyp-Hyp-valine-lysine" (See the abstract of Qi et al., Plant Physiol. (1995) 108: 1691-1701.) This article establishes that a person skilled in the art understands the applicant's claimed term "being absent a tetra-hydroxyproline block."

The Li et al. article describes an "[a]ssay for cross-linkage of sugar beet extensin. . . ." (See page 328 at the bottom of the first column of the article from Li et al. Plant Physiol. (1990) 92, 327-333.) This article demonstrates that a person skilled in the art understands assays for extensin and can derive and test concentrations of extensin.

Claim 6 in particular overcomes this rejection because it recites a specific peptide sequence. Therefore, the absence of a tetra-hydroxyproline block is defined by reciting the exact sequence without this limitation.

The appellant asks the Board to reverse the Examiner's final rejection of claims 4 through 9 under 35 U.S.C. § 112, second paragraph.

B. Rejection Under 35 U.S.C. § 102(b)

The Examiner rejects claims 4 through 9 under 35 U.S.C. § 102(b) as being anticipated by the prior art.

because the Examiner's newly cited article does not disclose

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all the elements of the appellant's claims. The Examiner has only presented a rejection based upon anticipation. No rejection under obviousness was presented, and no arguments against obviousness were made.

The appellant describes his invention on page 14 of the application at lines 2 through 5 and at lines 20 and 21 as desirably being a composition of "partly purified" extensin that lacks the tetra-hydroxyproline block. The appellant's partly purified extensin has the unexpected result of enhancing cytotoxic activity of lymphocytes as described in the application on page 11 at lines 9 and 10.

The Examiner's cited article does not disclose the appellant's claimed composition of a pharmaceutically active concentration of extensin sufficient for cytotoxic enhancement of lymphocytes. Further, the article does not disclose the claimed therapeutic activity for the composition. The article to Li et al., therefore, does not anticipate the appellant's claimed extensin.

The appellant's claims 5 and 7 through 9 are separately patentable because these claims recite specific fiber or pectin sources for the composition of claim 4. The Examiner's citation does not address these desirable combinations of claimed elements.

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§ 102(b). The Examiner has not cited a single reference that discloses all of the appellant's claimed elements.

C. Other Errors

The appellant also requests reversal of the Examiner's final Office Action for three technical errors. It is maintained that the Board should return the application to the Examiner for further prosecution, before the Board considers this appeal, because of these three technical errors.

The appellant twice requested an interview with the Examiner. No interview was offered or granted.

The appellant's amendment to claim 4 in the response of April 4, 2002, only presented amendments to overcome the Examiner's rejection under 35 U.S.C. § 112, second paragraph. The proffered amendments were definitions from the application that were always before the Examiner. The Examiner refused entry stating that a "new search" would be required. However, the Examiner presented a new citation of art, apparently from a new search.

The appellant also objects to the facts that the Examiner substituted a new citation of art and made the rejections of the claims "final." The Examiner never established a basis for the necessity of this new citation. The proffered amendments were not entered by the Examiner, therefore, it is

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Conclusion

Favorable consideration of the appeal and application is requested.

Respectfully submitted,

5 Aug 2002

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APPENDIX

Pending claims 4 through 9 are the subject of the appeal.

4. A composition comprising:

a protein of extensin, said protein being absent a tetra-hydroxyproline block and in a pharmaceutically active concentration sufficient for cytotoxic enhancement of lymphocytes.

5. The composition of claim 4 wherein said protein of extensin is sugar beet extensin.

6. The composition of claim 5 wherein said protein of extensin includes a sequence

Ser-Hyp2-X-Hyp2-Thr-Hyp-Val-Tyr-Lys

wherein X represents an insertion of Val-His-Glu or Lys-Tyr-Pro.

7. The composition of claim 4 further comprising sugar beet fiber.

8. The composition of claim 4 further comprising sugar beet pectin.

9. The composition of claim 6 further comprising pectic polysaccharides.